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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License, Inter-Institutional Agreement-Institution

Lead: Engineered Influenza Neuraminidase Antigens

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institute of Allergy and Infectious Diseases (NIAID), an institute of the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is contemplating the grant of an exclusive, sublicensable patent license to the University of Washington, located in Seattle, State of Washington, U.S.A. in its rights to the inventions and the patent applications listed in the Supplementary Information section of this notice.

DATES: Only written comments and/or applications for a license which are received by the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases (NIAID) on or before [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated exclusive patent license should be directed to: Amy Petrik, Technology Transfer and Patent Specialist, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Suite 6D, MSC9804, Rockville, MD 20852-9804, phone number 240-627-3721, or amy.petrik@nih.gov.

SUPPLEMENTARY INFORMATION: The following and all continuing patents/patent applications thereof are the intellectual property to be licensed under the prospective agreement to the University of Washington: United States Provisional Patent

Application Number 62/986,295, filed March 6, 2020, entitled "Engineered Influenza Neuraminidase Antigens" (HHS Reference No. E-052-2021-0-US-01) and Patent Cooperation Treaty (PCT) Patent Application Number PCT/US2021/020804, filed March 4, 2021, entitled "Engineered Influenza Neuraminidase Antigens" (HHS Reference No. E-052-2021-0-PCT-02).

The patent rights in these inventions have been assigned to the University of Washington and Government of the United States of America as represented by the Secretary, Department of Health & Human Services.

The prospective patent license will be for the purpose of consolidating the patent rights to the University of Washington, the co-owners of said rights, for commercial development and marketing.

Consolidation of these co-owned rights is intended to expedite development of the invention, consistent with the goals of the Bayh-Dole Act codified as 35 U.S.C. 200–212.

The prospective inter-institutional agreement may include an exclusive license for NIAID's rights in these jointly owned patent applications. It will be sublicensable, and any sublicenses granted by the University of Washington will be subject to the provisions of 37 CFR part 401 and 404.

In the subject technology, researchers at NIAID and the University of Washington engineered the neuraminidase glycoprotein from the influenza virus to improve its properties as an antigen. The patent applications claim the mutations that the researchers introduced to stabilize the neuraminidase protein in its closed conformation and use of the engineered protein in an influenza vaccine.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will include a share of the royalties from the licensing of this invention back to the NIAID, and may be granted unless within fifteen (15) days

from the date of this published notice, NIAID receives written evidence and argument

that establishes that the grant of the license would not be consistent with the requirements

of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments

and objections, other than those in the form of a license application, will not be treated

confidentially, and may be made publicly available.

Complete license applications submitted in response to this Notice will be presumed to

contain business confidential information and any release of information in these license

applications will be made only as required and upon a request under the Freedom of

Information Act, 5 U.S.C. 552.

Dated: April 25, 2022.

Surekha Vathyam,

Deputy Director,

Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.

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